EXHIBIT C

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FDA

DEPARTMENT OF HEALTH & HUMAN SERVICES — Food and Drug Administration

NEW ENGLAND DISTRICT

MEMORANDUM

Date February 24, 2003

From Kristina Joyce, Consumer Safety Officer, NWE-DO / FDA
Mark Lookabaugh, Compliance Officer, NWE-DO / FDA

Subject February 5, 2003 Meeting with Massachusetts Board of Pharmacy / Division of Professional Licensure (239 Causeway Street, Boston, MA 02114).

To Central File

Firm: New England Compounding Center
697 Waverly Street
Framingham, MA
FEI: 3003 623 877

Background

This meeting was arranged at the request of Mark Lookabaugh, NWE-DO Compliance Officer, via email to Charles Young, Executive Director, on January 30, 2003. The meeting was held to review the inspectional history of the New England Compounding Center and develop a joint strategy for achieving safe compounding practices at the firm.

In attendance at the meeting were:

Representing the New England District—

Gail Costello, District Director
David Elder, Compliance Branch Director
Mark Lookabaugh, Compliance Officer
William Boivin, Supervisory Consumer Safety Officer
Kristina Joyce, Consumer Safety Officer

Representing the Office of Compliance, CDER (via teleconference)—

Fred Richman, OC / DNDLC
Kathleen Anderson, OC / DNDLC
Betty Hiner, ORO / DFSR

Representing the Commonwealth of Massachusetts—

Jean Pontikas, Director, Division of Professional Licensure
Charles Young, Executive Director, Board of Pharmacy
James Coffey, Associate Director, Board of Pharmacy
Leslie Doyle, Supervisory Investigator, Board of Pharmacy
James Emery, Investigator, Board of Pharmacy
Susan Manning, Legal Counsel, Board of Pharmacy

Note: This memorandum has been prepared in accordance with Staff Manual Guide FDA 2126.2

Summary of Meeting

Mr. Young and Mr. Lookabaugh facilitated introductions.

Mr. Lookabaugh began with an overview of the inspectional history of New England Compounding Center (NECC). This included a brief description of the recent regulatory history of Pharmacy Compounding.[1]

William Boivin and Kristina Joyce then presented a table summarizing the results of FDA's current sample analyses.[2] Mr. Boivin and Ms. Joyce discussed current investigational findings.[3] It was stated that the FDA's next step would be to notify the firm of the violative sample results and inquire of his intentions regarding the violative product still in commerce. It was anticipated that the firm would initiate a voluntarily recall of the violative product.[4] If NECC does not take action regarding the violative lot, then depending on the quantities of the lot available FDA may initiate a seizure of the product. A Form FDA-483 (List of Inspectional Observations) will be issued to NECC with state representatives present at the FDA closeout meeting with NECC. Fred Richman and Kathleen Anderson reminded everyone that in a similar situation with a South Carolina compounding pharmacy, FDA issued a press release when the firm failed to take recall action in a timely manner.

A discussion was held to decide if NECC should be considered a manufacturer or a compounder. It was decided that current findings supported a compounding role. The FDA discussed their ability to take action (through seizure) against the adulterated lot of Betamethasone that is still within expiry. The issues of NECC's poor compounding practices would not necessarily be ultimately resolved by such an action. It was decided that the state would be in a better position to gain compliance or take regulatory action against NECC as necessary. The state favored recall of the violative product

[1] See Attachment 1.
[2] See Attachment 2.
[3] See Form FDA-483 (Inspectional Observations), Attachment 3.
[4] The firm has committed to recall this product.

within expiry. The state does not have the authority to subpoena records without cause or to embargo product, but agencies within their umbrella may be able to provide assistance in those matters. The state would ask Mr. Cadden, owner of NECC, to appear before the Board of Pharmacy to answer to the current complaints.

Leslie Doyle stated that NECC is licensed as a pharmacy provider in the following states—South Carolina, Florida, Virginia, Missouri, Maine, Rhode Island, New Hampshire, Nebraska, Idaho, and Montana. NECC is pursuing licensure in Connecticut, Ohio, Vermont, and Kansas.

Susan Manning stated Massachusetts pharmacy law states that pharmacists must act in accordance with USP recommendations. She stated this alone would imply he could be held to those standards by the state. She requested of the FDA a list of the current inspectional observations and where NECC differs from acceptable practice per USP standards. It was decided that Ms. Anderson would work on documenting the deviations from USP standards for the state. Ms. Manning stated although the state's authority does not include the ability to fine pharmacists, the state is able to take actions against a pharmacy's license, including revocation and suspension.

The state's pharmacy compounding regulations that are under review are a blend of USP standards and regulations from three other states that already have such regulations in place (including Georgia and South Carolina).

The state requested the following information[5] from the FDA:

- Examples of previous Consent Agreements
- MedWatch reports regarding Adverse Events from products compounded by NECC.
- A list of NECC deviations from acceptable practice (referring to FDA's inspectional findings)
- Previous and current FDA 483 (List of Observations) issued to NECC, with available documentation to support the findings.
- Copies of FDA EIRs for NECC (April 2002 and current inspection when available)
- Analytical Worksheets for sample collection and analysis.
- Copy of regulatory action taken by the FDA against Professional Compounding Centers of America (PCCA).

Summary.

Mr. Elder concluded the meeting by summarizing the discussions and emphasizing the potential for serious public health consequences if NECC's compounding practices, in particular those relating to sterile products, are not improved. The point was made that, so long as a pharmacy's operations fall within the scope of the practice of pharmacy (as

[5] This information was forwarded to the Board of Pharmacy (to the attention of Ms. Manning) via Federal Express on February 11, 2003.

Should be in State's file

outlined in FDA's Compliance Policy Guide 460.200), FDA will generally continue to defer to state authorities for regulatory oversight. In such cases FDA will seek to engage cooperative efforts aimed at achieving regulatory compliance and ensuring the safety and quality of compounded products.

Kristina Joyce
Consumer Safety Officer
New England District, FDA

Mark Lookabaugh
Compliance Officer
New England District, FDA

Attachments (3)

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MCL
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Reading File
Legal Reading File

Richman (HFD–310)
Anderson (HFD–310)

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